


# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ACH76726WO00		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP2004/014478	International filing date (day/month/year) 20.12.2004	Priority date (day/month/year) 13.02.2004	
International Patent Classification (IPC) or both national classification and IPC INV. A61K9/00 A61K31/192 A61K47/18 A61P11/04 A61P29/00 A61K31/196			
Applicant THERAPICON SRL			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 5 sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand  13.12.2005		Date of completion of this report  10.05.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Giacobbe, S  Telephone No. +49 89 2399-8463	



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP2004/014478

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

### Description, Pages

1-28 as originally filed

### Claims, Numbers

1-14 received on 15.12.2005 with letter of 13.12.2005

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
  - ☐ the language of publication of the international application (under Rule 48.3(b)).
  - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
  - ☐ filed together with the international application in computer readable form.
  - ☐ furnished subsequently to this Authority in written form.
  - ☐ furnished subsequently to this Authority in computer readable form.
  - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
  - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-14
Inventive step (IS)	Yes: Claims	
	No: Claims	1-14
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

### 2. Citations and explanations

**see separate sheet**

## **1. Section I**

The claims of the present application are restricted to two particular NSAIDS, whereas the description (cv. e.g. p. 6, l. 16 and ff.) describes the invention in much more general terms. The present search has been carried out on the claimed subject-matter, since only for this subject-matter does the description provide a sufficient disclosure (Art 5 PCT).

## **2. Section V**

### **2.1 Cited Documents**

The following documents (D) are referred to in this Opinion; the numbering will be adhered to in the rest of the procedure:

D1: WO 03/094905 A (AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO A.C.R.A.F. S.P.A; PINZA, M) 20 November 2003

D2: HOLZER P ET AL: "Estimation of acute flurbiprofen and ketoprofen toxicity in rat gastric mucosa at therapy-relevant doses" INFLAMMATION RESEARCH, vol. 50, no. 12, 2001, pages 602-608, XP001204998

D3: US-A-5 183 829 (CALDWELL ET AL) 2 February 1993

Unless otherwise indicated reference is hereafter made to the passages cited in the Search Report.

### **2.2 The prior art**

2.2a Document D1 discloses buccal sprays comprising diclofenac and tromethamine. Also all other claimed ingredients are disclosed.

2.2b Document D2 discloses solutions of racemic flurbiprofen and of its enantiomers in saline. The solutions are suitable for spraying into the oral cavity (compare present description, p. 1, l. 7).

2.2c Document D3 discloses oral solutions comprising diclofenac or flurbiprofen in the form of their tromethamine salt. The solutions are suitable for spraying into the oral cavity (compare present description, p. 1, l. 7).

### **2.3 Art 33(2) PCT (Novelty)**

The subject-matter of claims 1-14 of the present application does not meet the requirements of Article 33(2) PCT.

The subject-matter of these claims is anticipated by the cited passages of documents D1-D3. In this respect it is observed that the functional definition of ingredient (b) in the present claims does not limit in any way the overall scope of the claim, so that any prior art composition comprising ingredients (a) and (d), D-glucamine, meglumine or trometamol (or mixtures thereof), and having, explicitly or implicitly, a pH as in point (c), are novelty-destroying for at least claim 1.

#### **2.4 Art 33(3) PCT (Inventive step)**

Since the question of the presence of an inventive step only arises when the subject-matter is new, a more detailed analysis of the compliance of the present application with the requirements of Art 33(3) PCT is postponed until the objections above are overcome. It however appears that the technical problem solved by the present invention is the provision of stable solutions (point (b) on p. 3), since all the other problems (a) and (c)-(f) listed on the same and the following page are either already solved in the art (point (a)) or are solved by optional ingredients of the present formulations (points (c)-(f)). This is the same problem as the one solved by at least D1 (cf. 2, ll.13-20). Document D1 is therefore the closest prior art document.